REMARKS

Applicants hereby respond to the Restriction Requirement mailed on May 5, 2009 within the First Month Extension of the shortened statutory response period of 1 month set in that Office Action.

<u>Amendments</u>

Claims 1 to 8, and 16 are hereby cancelled without prejudice to renewal. Applicants have submitted new claims 20 to 26 and currently amended claims 10, 15, 17, 18 and 19.

Applicants have thus reformulated the claim structure to focus on a particularly preferred compound of the invention in an effort to advance prosecution of the subject application.

Applicants stress that there is no art rejection of record and this preliminary focus of claim scope should not be interpreted as ceding any right to pursue other inventions disclosed in this application as filed, either in this or a subsequent application.

The compound named in new claim 20 and its structure find direct support in written description set forth in original disclosure such as original claim 8 and Example 2 at pages 28 and 29 of the specification as filed. The pharmaceutically acceptable salt forms described in claims 20 to 24 find direct support in written description set forth in original disclosure such as original claim 1 and page 4, lines 4 to 8 of the specification as filed. New claim 23 and 24 find direct support in original disclosure such as Procedure III set forth on page 29, lines 11 to 19 of the application as filed. New claims 25 and 26 find direct support in original disclosure such as at pages 6 and 7.

Applicants respectfully submit that these amendments are fully supported by original disclosure and do not introduce new matter. Entry of the amendments is respectfully requested.

Traverse of Restriction

The Office Action of May 5, 2009 set forth a Restriction Requirement, requiring election among:

- Group I, claims 1-8 and 10, drawn to a chemical compound and a pharmaceutical composition of Formula I;
- Group II, claims 15-19, drawn to a method of treating a disorder or disease using a composition of Formula I; and
- Group III, claims 15-19, drawn to a method of preventing a disorder or disease using a composition of Formula I.

Applicants respectfully traverse this restriction requirement on the ground that the examination of the compound claims <u>does</u> relate to a common structure. The core structure Formula I, to which all of the claims relate provides a definite, confined range of structural alternatives for purpose of conducting an orderly and efficient search and examination.

Applicants respectfully submit that the inclusion of a minor range of variation within this core structure at R1, R2, R3 and X does not move the claims outside the applicable unity o f invention standard an does not introduce undue complexity to the subject matter to be examined.

Indeed, X introduces only 2 ring structure alternatives to the core structure, and the described substituent variation is not unduly or burdensomely extensive; R1 and R2 are independently either hydrogen or C1-C4 alkoxy, and R3 only describes the use of C1-C6 alkyl groups. Applicants respectfully submit that the subject matter encompassed by the broadest claim does not present an undue search burden and the claims as a whole are closely related through this well-defined structural core.

Applicants respectfully submit that this reasonable degree of variation, at a limited number of points in the core structure which defines the invention, reflects a single general inventive concept within the meaning of PCT Rule 13.1. Such variation is specifically contemplated as set forth in PCT Rule 13.4:

13.4 Dependent Claims

Subject to Rule 13.1, it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention.

Moreover, the restriction requirement does not define three independent and distinct groups, since Groups II and Groups III relate to the administration of the claimed compounds of Group I.

The proposed division drawn here between preventative and therapeutic administration of the claimed compounds creates a bright-line schism between subject matter which would call for an idealized view of the practice of examining physicians, which to the contrary is always limited by the effectiveness and availability of appropriate diagnostic techniques. The physician's professional judgment is often exercised in that challenging range represented by less than a fully confident diagnosis regarding the incontrovertible presence of an active condition in a patient whom the physician none the less judges to be in need of medicinal intervention.

It is therefore respectfully submitted that to be maintained, the proposed restriction requirement would require a broader gulf between the proposed Groups II and III. When such a physician identifies that a patient is in need of medicinal intervention there may be no bright line distinction between treating a minor presentment of a condition or instead preventing the onset of a fully confidently diagnosable state of the condition.

In such cases, when the physician administers the claimed compound, the invention contributed to medicine by the Applicants would be practiced. That critical stage of medical practice represents the definite articulated linkage that justifies examination of both Groups II and III at the same time, and both would most effectively be examined along with Group I.

Provisional Election

In the event that the Examiner maintains the Restriction Requirement, and reserving all rights, including the right to reinstatement or rejoinder of any claims and/or scopes in the event the restriction requirement is withdrawn or a generic claim is allowed, and/or the right to pursue any non-elected or cancelled inventions in divisional applications, Applicants provisionally restrict, with traverse, Group I of the restriction requirement. After the presently requested amendments are entered, claims 10, 20, 21, 22, 23 and 24 will be the pending claims relating to the chemical compound and pharmaceutical composition of defined Group I.

Since this response is being filed within the first month after the shortened one-month statutory period set in the restriction requirement mailed on May 5, 2009, a petition for one-month extension of time is filed herewith. If other fees are deemed to be due, however, the Commissioner is authorized to charge any additional fees, or credit any overpayment, to Deposit Account No. 50-4255.

Respectfully submitted,

Date Jone 9, 2009

Brian W. Stegman Reg. No. 30,977

Hoxie & Associates LLC 75 Main Street, Suite 301 Millburn, NJ 07041 973-912-5232 phone 973-912-5236 fax